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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,605

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Kosaburo Wakamatsu

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EXAMINER

KAROL, JODY LYNN

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,605	Applicant(s) WAKAMATSU ET AL.	
	Examiner Jody L. Karol	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/30/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7-12,15,17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7-12, 15, and 17-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' Amendments and Remarks submitted on 4/30/2008 have been entered. Claims 2-4, 6, 13-14, 16, and 19-20 are cancelled and claims 1, 12 and 17-18 have been amended. Accordingly, claims 1, 5, 7-12, 15 and 17-18 are pending and examined on the merits herein.

Status of Objections/Rejections

1. In view of Applicants' amendments to the specification, the objection to the specification is herein withdrawn.
2. In view of Applicants' amendment to claim 1, and cancellation of claim 20, the objections to the claims are herein withdrawn.
3. The provisional rejection of claims 1 and 5, and 7-11 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 5-6 of copending Application No. 11/722965 is maintained. The rejection of claims 3 and 6 is moot in view of Applicants' cancellation of these claims.
4. The rejection of claims 12-13 and 15-20 under 35 U.S.C. 112 as being indefinite is herein withdrawn in view of Applicants' amendments to claims 12, 15, and 17, and in view of the cancellation of claims 13, 16, and 19-20.

5. The rejection of claims 19-20 under U.S.C. 101 is moot in view of Applicants' cancellation of claims 19-20.

6. The rejection of claims 1, 10, and 11 under 35 U.S.C. 102(a) as anticipated by www.nuinternational.co.jp/seibun.html+AMP is herein withdrawn in view of Applicants' amendment to claim 1.

7. Applicants' arguments regarding the rejection of claims 1, 3, 5-13, and 15-18 under 35 U.S.C. 103(a) as obvious over Wakamatsu et al. (WO 02/41853) in view of Castiel et al. (US 2002/0042380 A1) have been fully considered but not found persuasive. Thus the rejection is maintained, but has been modified to address Applicants' amendments to the claims. The rejection in so much as it pertains to claims 3, 6, 13 and 16 is moot in view of Applicants' cancellation of these claims.

8. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied in the instant application.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 5 and 7-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-6 of copending Application No. 11/722965.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims sets are directed to composition comprising an adenosine monophosphate and an ascorbic acid derivative, such as ascorbic-2-glucoside. There are additional components present in the compositions of the copending claims. However, the term "comprising" is interpreted as broad and open-ended, and other components not mentioned may be present in the compositions of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 1, 3, 5-13, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakamatsu et al. (WO 2002/41853) in view of Castiel et al. (US 2002/0042380 A1). US 6,946,436 B2 is used as the English equivalent of Wakamatsu et al. (WO 2002/41853).

Claims 1, and 5 and 7-11 are directed to compositing comprising ascorbic acid 2-glucoside and an adenosine monophosphate (AMP). Claim 5 specifies that the AMP is adenosine 5'-monophosphate or salt thereof. Claims 7-9 further limit the amount of the components.

Wakamatsu et al. teach an O/W emulsion composition comprising an electrolyte, where the preferred electrolytes are adenosine monophosphate, cyclic adenosine monophosphate, salts thereof, ascorbic acid, and derivatives thereof (see column 7, lines 9-36 and claims 3-4). The adenylic acid derivatives (i.e. adenosine monophosphate) are known to exhibit moisturizing and anti-aging effects when applied to the skin (see column 7, lines 45-54 and column 16, lines 1-15). The placing of the phosphate group of adenosine monophosphate (AMP) is not specified, however, a phosphate group can only attach on an adenosine molecule where there is a hydroxyl group. Hydroxyl groups are present on adenosine at the 2', 3' and 5' positions, so the AMP must be adenosine 2'-monophosphate, adenosine 3'-monophosphate, adenosine

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5'-monophosphate, or mixtures thereof. Wakamatsu et al. further teach that the electrolytes can be used alone or in combination of two or more species (see column 7, lines 39-40) and the amount of electrolytes contained in the composition is not limited, but is at least 0.1% by weight, and preferably 0.5 to 7% by weight as claimed in the instant claims 7-9 (see column 7, line 66 to column 8, line 5 and claims 12-14).

Wakamatsu et al. teaches specific examples where adenosine monophosphate disodium is present in the composition in 1.5%, 3.0% and 6.0% by weight (see Table 1, examples 1-4) and where sodium L-ascorbic acid phosphate ester (L-ascorbyl phosphate salt) is present in the composition in 2.0 and 3.0% by weight (see Table 1, examples 5-6).

Wakamatsu et al. do not explicitly teach a compositions comprising the AMP and ascorbic acid derivative, or the method of applying the herein claimed composition to the skin to prevent aging as claimed in the instant claims 12, 15, and 17-18.

Wakamatsu et al. also does not teach the function of ascorbic acid derivatives or ascorbic acid 2-glucoside as an ascorbic acid derivative. Wakamatsu et al. does not explicitly teach adenosine 5'-monophosphate.

Castiel et al. teaches Vitamin C derivatives more stable than ascorbic acid itself and which combat or prevent intrinsic aging of the skin (see abstract). One of the preferred ascorbic acid derivatives is a 2-O- α -D-glucopyranosyl of ascorbic acid, also known as ascorbic acid 2-glucoside (see page 2, sections 32, 35, and 41). Castiel et al. further teaches the compositions contain 0.001 to 10% by weight of ascorbic acid derivatives (see page 2, section 42), and gives an example of composition with

ascorbic acid 2-glucoside present in 0.1% by weight of the composition (see page 4, section 77).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine adenosine monophosphate with another electrolyte, such as an ascorbic acid derivative, as taught by Wakamatsu et al., wherein the ascorbic acid derivative is ascorbic acid 2-glucoside as taught Castiel et al. One of ordinary skill in the art would have been motivated to do so in order to formulate a composition with anti-aging action, since adenosine monophosphate derivatives and ascorbic acid derivatives are both used individually in the art for the same purpose, namely to keep skin from aging. It is obvious to one of ordinary skill in the art to combine components taught individually in the art as having the same purpose to form a new composition for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 205, U.S.P.Q. 1069 (C.C.P.A. 1980). Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention that the composition made obvious by Wakamatsu et al. in view of Castiel et al. would be applied to the skin for its intended use to prevent aging.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

13. In response to Applicants' arguments filed 4/30/2008 asserting that the AMP taught by Wakamatsu et al. and the ascorbic acid derivatives taught by Castiel et al. are taught not to have the same purpose, the Examiner respectfully disagrees. AMP is

taught by Wakamatsu et al. to have a moisturizing effect and stimulate cell turnover, thereby preventing aging of the skin (see column 7, lines 45-54). Ascorbic-2-glucoside is taught by Castiel et al. to augment epidermal lipogenesis, improve the barrier function of the skin permitting better retention of water (i.e. skin moisturizer), improve the suppleness of the skin, and/or combat prevent intrinsic aging of the skin (see page 3, sections [0044]-[0045]). Thus, while the AMP and ascorbic-2-glucoside may combat aging by different mechanisms, both are recognized in the art as useful for the same purpose of preventing aging of the skin.

14. In response to Applicants' argument that the selection of ascorbic acid or derivative thereof from the selection of electrolytes provided by Wakamatsu et al. is based on improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). From the teachings of Wakamatsu et al., one of ordinary skill in the art would have reasonably selected any of the disclosed electrolytes, including ascorbic acid derivatives, absence any showing of unexpected results or the criticality of employing ascorbic acid derivatives. One of ordinary skill in the art would then be motivated to use the ascorbic-

2-glucoside as the ascorbic acid derivative because it is taught by Castiel et al. to be more stable than ascorbic acid.

15. In response to Applicants' remark that a synergistic effect exists between AMP and ascorbic-2-glucoside, it is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the evidence presented is not of a scope reasonably commensurate with the scope of the subject matter claimed. Only one specific comparative example is provided on pages 22-24 of the instant specification, and in Figure 1, as evidence for combining ascorbic-2-glucoside and AMP in isopropanol to synergistically potentiate the effect of alleviating pigment, which is not necessarily attributed to an anti-aging effect. The example also does not provide sufficient evidence that the remaining composition formulations possible under the claim scope would exhibit the same or similar results, or potentiate antiaging action in general. Therefore, no clear and convincing unexpected benefit is seen to be present herein. Thus, the instant claims are still considered properly rejected under 35 USC 103(a).

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JLK

/San-ming Hui/
Primary Examiner, Art Unit 1617

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